UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

March 17, 2016

MEMORANDUM

Subject: Efficacy Review for Backspin No-Rinse FCSS; EPA File Symbol 9480-RG; DB Barcode: D430054.

From: Ibrahim Laniyan, Ph.D.
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Thru: Mark Perry, Team Leader
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To: Eric Miederhoff RM31 / Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Professional Disposables International, Inc. (POI)
Two Nice-Pak Park
Orangeburg, NY 10962-1376

Formulation from the Label:

Active Ingredient	% by wt.
Didecyl dimethyl ammonium chloride	0.023 %
Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride	0.015 %
Other Ingredients:	99.962 %
Total	100.000 %

I. BACKGROUND

The product, Backspin No-Rinse FCSS (EPA File Symbol 9480-RG), is a new product. The applicant requested to register the product as a sanitizer for food and non-food contact hard, non-porous surfaces in household environments, industrial areas commercial, food processing. According to registrant, Backspin No-Rinse FCSS is a sanitizing wipe for hard nonporous food and nonfood contact surfaces. With the exception of the towelette material, the formulation is identical to the Backspray RTU (9480-RR), which is currently being reviewed at EPA.
To support Backspin No-Rinse FCSS organism claims on the label, registrant is citing efficacy studies conducted on the Backspray RTU (9480-RR) for those specific claims. In addition, registrant is submitting four studies for efficacy testing conducted on the towelette. Also enclosed is one study for testing conducted on the towelette as a non-food contact sanitizer. Studies were conducted at MycoScience Labs, Inc., located at 25 Village Hill Rd, Willington, CT 06279; and Accuratus Lab Services, located at 1285 Corporate Center Drive, Suite 110
Eagan, MN 55121.

This data package, identified as D430054, contained a letter from the applicant representative to EPA (dated October 20, 2015), EPA Form 8570-35 (Data Matrix), eleven studies under five MRID Nos. (497464-03 through 497464-07), Statements of No Data Confidentiality Claims for eleven studies, and the proposed label (dated October 7, 2015).

II. USE DIRECTIONS

TO SANITIZE [HARD NON POROUS FOOD-CONTACT SURFACES]:
For Lightly Soiled Surfaces: Use a *[product* name] wipe to clean the surface to be treated. Sanitize with additional [product name] wipes. Wipe enough for treated area to remain wet for one [1] minute [or 60 seconds]. Let air dry. No rinsing required.
For heavily soiled surfaces: Remove all food particles and soil from surfaces that are to be sanitized by thoroughly washing the surfaces with a detergent, followed by a potable water rinse before applying this [sanitizing wipe] *[product* name]. Wipe enough for treated area to remain wet for one [1] minute [or 60 seconds]. Let air dry. No rinsing required.
99.999% effective in one [1] minute [or60 seconds] in the presence of 5% organic soil against *Escherichia coli* [(ATCC # 11229)], *Staphylococcus aureus* [(ATCC #6538)], *Shigella boydii* [(ATCC #9207)], and *Listeria monocytogenes* [(ATCC #19115)].

[TO SANITIZE] [HARD NONPOROUS NONFOOD-CONTACT SURFACES]:
[Cleaning and] Sanitizing Procedure: Use a *[product name]* wipe to clean the surface to be treated. Sanitize surface with *[product* name] wipes. Wipe enough for treated area to remain wet for one [1] minute *[or* 60 seconds]. Let air dry. No rinsing required.
99.9% effective in 15 seconds against *Staphylococcus aureus* (ATCC #6538) and *Enterobacter aerogenes* (ATCC # 13048) [in the presence of organic soil (5% blood serum)].

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Antimicrobial Products for Use on Hard Surfaces Using Pre-saturated or Impregnated Towelettes: Towelette products represent a unique combination of antimicrobial chemical and applicator, pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to the directions for use to ensure the product's effectiveness in treating hard surfaces. The standard test methods available for hard surface disinfectants and

sanitizers, if followed exactly, would not closely simulate the way a towelette product is used. Agency guidelines recommend that a simulated-use test be conducted by modifying the standard test methods. Agency guidelines further recommend that instead of spraying the inoculated surface of the carrier, the product should be tested by wiping the surface of the carrier with the saturated towelette, and then subculturing the slides after a specified holding time. Performance standards of the standard test methods must be met. These Agency standards are presented in OCSPP 810. Guidelines, Pre-saturated or impregnated towelettes; and the April 12, 2001 EPA Memorandum, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 497464-03 "PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: Staphylococcus aureus (ATCC 6538) Glass and Rough Plastic- 4ft.^{2}" for Backspin No-Rinse FCSS, by Richard Arsenault. Study conducted at MycoScience Labs, Inc. Study completion date – June 15, 16, and 17, 2015. Project Number 15-0079 NPNY, 15-0172 NPNY, and 15-0277 NPNY.

These studies were conducted against *Staphylococcus aureus* (ATCC 6538). Three lot (Lot No. 7912-AE-937-004A, 7912-AE-937-004B, and 7912-AE-937-004C) of the product, Backspin No-Rinse FCSS, were tested according to MycoScience Labs protocols GLP-15-001 Rev.00, GLP-15-005 Rev.00, and GLP-15-010 Rev.00 (copies provided), against the target microorganisms for a contact time of 30 seconds at 20-23°C and 10 - 19% RH. Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. A 2' x 2' (4ft^2) surface was comprised of eight 6" x 12" glass or rough plastic surface sections. Each 6" x 12" surface was inoculated with 0.125mL of the prepared culture suspension so that the total inoculum volume was 1.0 rnL per 2' x 2' (4ft^2)) total surface area. The inoculum was spread uniformly over each surface section using a sterile spreading stick. The inoculated surfaces were dried for 30 minutes at room temperature and humidity in a biological safety cabinet. The 2' x 2' (4ft^2) surfaces were inoculated and tested in triplicate for both smooth glass and rough plastic for each lot. One 8" x 10" wipe was used to wipe an entire 2' x 2' (4ft.^{2}) inoculated surface. The wipe was folded in half two times prior to wiping the first 6" x 12" surface section. Each surface section was wiped in a consistent manner up and down the surface and working from left to right across the entire surface, then back from right to left. This was repeated one additional time so that the entire inoculated 6" x 12" surface had been wiped in this manner two times. The wipe was rotated and re-folded as necessary for each surface section wiped, so that the maximum of wipe surface was used over the course of wiping an entire 2' x 2' surface. After contact time, each surface was transferred to a sterile composite bag containing 3,000mL of AOAC neutralizing blank solution. The wipe was transferred into a sterile jar containing 200mL of AOAC neutralizing blank solution. The composite bag containing the surface carriers was sonicated for 5 minutes in an ultrasonic bath, followed by thorough agitation by hand. Surface and wipe suspensions were assayed for surviving numbers of microorganisms using membrane filtration technique. 3mL and 30mL of the sample surface extract, and 2mL and 20mL of the wipe extracts were filtered through individual sterile bacterial retentive filters followed by a 50mL rinse with AOAC neutralizing blank solution. The membrane filters were transferred to the surface of Tryptone Glucose Extract Agar plates (TGEA-N), and were incubated for a minimum of 48 hours at 35-37°C, and then were enumerated. Controls included those for parallel positive control count, inoculum count, neutralization confirmation, purity, sterility, and viability. The final surface inoculum after drying was >7.5 x 10^7 CFU/ dried 2' x 2' (4ft^2) glass surface or rough plastic surface.

2. MRID 497464-04 "PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: *Escherichia coli* (ATCC 11229) Glass and Rough Plastic- 4ft.^{2}" for Backspin No-Rinse FCSS, by Richard Arsenault. Study conducted at MycoScience Labs, Inc. Study completion date – June 16, and 17, 2015. Project Number 15-0135 NPNY, 15-0320 NPNY, and 15-0659 NPNY.

These studies were conducted against *Escherichia coli* (ATCC 11229). Three lots (Lot Nos. 7912-AE-937-004A, 7912-AE-937-004B, and 7912-AE-937-047A) of the product, Backspin No-Rinse FCSS, were tested according to MycoScience Labs protocols GLP-15-004 Rev. 00, GLP-15-008 Rev. 00, and GLP-15-014 Rev. 00 (copies provided), against the target microorganisms for a contact time of 30 seconds at 20-23°C and 16-33% RH. Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. A 2' x 2' (4ft^2) surface was comprised of eight 6" x 12" glass or rough plastic surface sections. Each 6" x 12" surface was inoculated with 0.125mL of the prepared culture suspension so that the total inoculum volume was 1.0 mL per 2' x 2' (4ft^2)) total surface area. The inoculum was spread uniformly over each surface section using a sterile spreading stick. The inoculated surfaces were dried for 30 minutes at room temperature and humidity in a biological safety cabinet. The 2' x 2' (4ft^2) surfaces were inoculated and tested in triplicate for both smooth glass and rough plastic for each lot. One 8" x 10" wipe was used to wipe an entire 2' x 2' (4ft.^{2}) inoculated surface. The wipe was folded in half two times prior to wiping the first 6" x 12" surface section. Each surface section was wiped in a consistent manner up and down the surface and working from left to right across the entire surface, then back from right to left. This was repeated one additional time so that the entire inoculated 6" x 12" surface had been wiped in this manner two times. The wipe was rotated and re-folded as necessary for each surface section wiped, so that the maximum of wipe surface was used over the course of wiping an entire 2' x 2' surface. After contact time, each surface was transferred to a sterile composite bag containing 3,000mL of AOAC neutralizing blank solution. The wipe was transferred into a sterile jar containing 200mL of AOAC neutralizing blank solution. The composite bag containing the surface carriers was sonicated for 5 minutes in an ultrasonic bath, followed by thorough agitation by hand. Surface and wipe suspensions were assayed for surviving numbers of microorganisms using membrane filtration technique. 3mL and 30mL of the sample surface extract, and 2mL and 20mL of the wipe extracts were filtered through individual sterile bacterial retentive filters followed by a 50mL rinse with AOAC neutralizing blank solution. The membrane filters were transferred to the surface of Tryptone Glucose Extract Agar plates (TGEA-N), and were incubated for a minimum of 48 hours at 35-37°C, and then were enumerated. Controls included those for parallel positive control count, inoculum count, neutralization confirmation, purity, sterility, and viability. The final surface inoculum after drying was >7.5 x 10^7 CFU/ dried 2' x 2' (4ft^2) glass surface or rough plastic surface.

3. MRID 497464-05 "PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: *Shigella boydii* (ATCC 9207) Glass and Rough Plastic- 4ft.^{2}" for Backspin No-Rinse FCSS, by Richard Arsenault. Study conducted at MycoScience Labs, Inc. Study completion date – June 19, 2015. Project Number 15-0678 NPNY, and 15-0682 NPNY.

These studies were conducted against *Shigella boydii* (ATCC 9207). Two lots (Lot Nos. 7912-AE-937-047B, and 7912-AE-937-047C) of the product, Backspin No-Rinse FCSS, were tested according to MycoScience Labs protocols GLP-15-015 Rev. 00, and GLP-15-016 Rev. 00 (copies provided), against the target microorganisms for a contact time of 30 seconds at 23-25°C and 30-44% RH. Fetal bovine serum was added to each inoculum to achieve a 5% organic soil

load. A 2' x 2' (4ft^2) surface was comprised of eight 6" x 12" glass or rough plastic surface sections. Each 6" x 12" surface was inoculated with 0.125mL of the prepared culture suspension so that the total inoculum volume was 1.0 rnL per 2' x 2' (4ft^2)) total surface area. The inoculum was spread uniformly over each surface section using a sterile spreading stick. The inoculated surfaces were dried for 25 minutes at room temperature and humidity in a biological safety cabinet. The 2' x 2' (4ft^2) surfaces were inoculated and tested in triplicate for both smooth glass and rough plastic for each lot. One 8" x 10" wipe was used to wipe an entire 2' x 2' (4ft.^{2}) inoculated surface. The wipe was folded in half two times prior to wiping the first 6" x 12" surface section. Each surface section was wiped in a consistent manner up and down the surface and working from left to right across the entire surface, then back from right to left. This was repeated one additional time so that the entire inoculated 6" x 12" surface had been wiped in this manner two times. The wipe was rotated and re-folded as necessary for each surface section wiped, so that the maximum of wipe surface was used over the course of wiping an entire 2' x 2' surface. After contact time, each surface was transferred to a sterile composite bag containing 3,000mL of AOAC neutralizing blank solution. The wipe was transferred into a sterile jar containing 200mL of AOAC neutralizing blank solution. The composite bag containing the surface carriers was sonicated for 5 minutes in an ultrasonic bath, followed by thorough agitation by hand. Surface and wipe suspensions were assayed for surviving numbers of microorganisms using membrane filtration technique. 3mL and 30mL of the sample surface extract, and 2mL and 20mL of the wipe extracts were filtered through individual sterile bacterial retentive filters followed by a 50mL rinse with AOAC neutralizing blank solution. The membrane filters were transferred to the surface of Tryptone Glucose Extract Agar plates (TGEA-N), and were incubated for a minimum of 48 hours at 35-37°C, and then were enumerated. Controls included those for parallel positive control count, inoculum count, neutralization confirmation, purity, sterility, and viability. The final surface inoculum after drying was >7.5 x 10^7 CFU/ dried 2' x 2' (4ft^2) glass surface or rough plastic surface.

4. MRID 497464-06 "PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: *Listeria monocytogenes* (ATCC 19115) Glass and Rough Plastic- 4ft.^{2}" for Backspin No-Rinse FCSS, by Richard Arsenault. Study conducted at MycoScience Labs, Inc. Study completion date – June 22, and 23, 2015. Project Number 15-0785 NPNY, and 15-0786 NPNY.

These studies were conducted against *Listeria monocytogenes* (ATCC 19115). Two lots (Lot Nos. 7912-AE-937-060A, and 7912-AE-937-060B) of the product, Backspin No-Rinse FCSS, were tested according to MycoScience Labs protocols GLP-15-017 Rev. 00, and GLP-15-018 Rev. 00 (copies provided), against the target microorganisms for a contact time of 30 seconds at 22-25°C and 31-44% RH. Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. A 2' x 2' (4ft^2) surface was comprised of eight 6" x 12" glass or rough plastic surface sections. Each 6" x 12" surface was inoculated with 0.125mL of the prepared culture suspension so that the total inoculum volume was 1.0 rnL per 2' x 2' (4ft^2)) total surface area. The inoculum was spread uniformly over each surface section using a sterile spreading stick. The inoculated surfaces were dried for 25 minutes at room temperature and humidity in a biological safety cabinet. The 2' x 2' (4ft^2) surfaces were inoculated and tested in triplicate for both smooth glass and rough plastic for each lot. One 8" x 10" wipe was used to wipe an entire 2' x 2' (4ft.^{2}) inoculated surface. The wipe was folded in half two times prior to wiping the first 6" x 12" surface section. Each surface section was wiped in a consistent manner up and down the surface and working from left to right across the entire surface, then back from right to left. This was repeated one additional time so that the entire inoculated 6" x 12" surface had been wiped in this manner two times. The wipe was rotated and re-folded as necessary for each surface section wiped, so that the maximum of wipe surface was used over the course of wiping an entire 2' x 2' surface.

After contact time, each surface was transferred to a sterile composite bag containing 3,000mL of AOAC neutralizing blank solution. The wipe was transferred into a sterile jar containing 200mL of AOAC neutralizing blank solution. The composite bag containing the surface carriers was sonicated for 5 minutes in an ultrasonic bath, followed by thorough agitation by hand. Surface and wipe suspensions were assayed for surviving numbers of microorganisms using pour plate technique. Appropriate aliquots, such as 3mL and 30mL of the sample surface extract, and 2mL and 20mL of the wipe extracts, were plated to tempered molten Brain Heart Infusion Agar (BHIA-N) containing stock AOAC neutralizer solution. 20mL and 30mL aliquots were plated by evenly splitting 10 rnL aliquot portions and plating to large 150mm x 15mm plates. 2mL and 3mL aliquots were plated directly to standard 100mm x 15mm plates. The plates were mixed thoroughly and allowed to solidify, and incubated for 48 +/- 2 hours at 36 +/- I °C. After the incubation period, the plates were enumerated. Controls included those for parallel positive control count, inoculum count, neutralization confirmation, purity, sterility, and viability. The final surface inoculum after drying was >7.5 x 10^7 CFU/ dried 2' x 2' ($4ft^2$) glass surface or rough plastic surface.

5. MRID 497464-07 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Pre-Saturated Towelette Product Application)" Test Organism: *Staphylococcus aureus* (ATCC 6538) for Backspin No-Rinse FCSS, by Jamie Herzan. Study conducted at Accuratus Lab Services. Study completion date – June 17, 2015. Project Number A18356.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. 7912-AE-937-047A, 7912-AE-937-0478, and 7912-AE-937-047C) of the product, Backspin No-Rinse FCSS, were according to Accuratus Lab Services protocol NPP01042415.NFS (copy provided). Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. The product was received ready to use. Five sterile glass carriers per organism were inoculated with 0.02 ml of a 48-54 hour old suspension of the test organism. The carriers were dried at 35-37°C at 40% relative humidity for 20 minutes. One towelette was used to treat 5 carriers. Each carrier was wiped with a saturated pad back and forth for a total of 4 passes. The product delivered by this wiping was allowed to remain on the carrier surface for 15 seconds at 20 °C and 53% RH. After exposure, each carrier was transferred to 20 ml of neutralizer using identical staggered intervals. The jars were vortex-mixed for10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 ml and 0.100 ml aliquots of the neutralized solution (10°) were plated onto the recovery agar plate medium. (Tryptic soy agar with 5% sheep's blood). The *S. aureus* plates were incubated at 35-37°C for 48±4 hours. The *E. aerogenes* plates were incubated for 48±4 hours at 25-32°C. Following incubation, the subcultures were visually enumerated. Controls included those for carrier quantitation, dry carrier count, inoculum count, neutralization confirmation, purity, sterility, and viability.

Note: Protocol amendments reported in the study were reviewed.

V. RESULTS

MRID #	Microorganism	Lot	Surface	CFU Recovered	Control Count	% Reduction
	Staphylococcus aureus	7912-AE-937-004A	Rough Plastic	<193.67	7.83 x 10^7	≥99.999%
			Smooth Glass	<476.67	7.85 x 10^7	≥99.999%
			Rough Plastic	<143.33	8.83 x 10^7	≥99.999%

497464-03	(ATCC # 6538)	7912-AE-937-004B	Smooth Glass	<116.67	1.01×10^8	≥99.999%
		7912-AE-937-004C	Rough Plastic	<176.67	1.24×10^8	≥99.999%
			Smooth Glass	9.36×10^2	2.58×10^8	≥99.999%
497464-04	*Escherichia coli* (ATCC # 11229)	7912-AE-937-004A	Rough Plastic	<120	8.10×10^7	≥99.999%
			Smooth Glass	<110	7.91×10^7	≥99.999%
		7912-AE-937-004B	Rough Plastic	180	1.04×10^8	≥99.999%
			Smooth Glass	<110	2.08×10^8	≥99.999%
		7912-AE-937-047A	Rough Plastic	280	1.37×10^8	≥99.999%
			Smooth Glass	<110	8.98×10^7	≥99.999%
497464-05	*Shigella boydii* (ATCC 9207)	7912-AE-937-047B	Rough Plastic	<1243.33	1.67×10^8	≥99.999%
			Smooth Glass	<110	2.24×10^8	≥99.999%
		7912-AE-937-047C	Rough Plastic	<143.33	1.84×10^8	≥99.999%
			Smooth Glass	<110	1.22×10^8	≥99.999%
497464-06	*Listeria monocytogenes* (ATCC 19115)	7912-AE-937-060A	Rough Plastic	1.36×10^3	4.44×10^8	≥99.999%
			Smooth Glass	896.67	2.56×10^8	≥99.999%
		7912-AE-937-060B	Rough Plastic	653.33	1.85×10^8	≥99.999%
			Smooth Glass	266.67	8.26×10^7	≥99.999%
497464-06	*Enterobacter aerogenes* (ATCC 13048)	7912-AE-937-047A	Glass carriers	<20	2.95×10^6	>99.9%
		7912-AE-937-0478		<20		>99.9%
		7912-AE-937-047C		<20		>99.9%
	Staphylococcus aureus (ATCC 6538)	7912-AE-937-047A		<20	75×10^6	>99.9%
		7912-AE-937-0478		<20		>99.9%
		7912-AE-937-047C		<20		>99.9%

VI. RESULTS

1. The following efficacy data **support** the use of the product, Backspin No-Rinse FCSS (EPA File Symbol 9480-RG), as a food contact surface sanitizer against the following microorganisms for a contact time of 30 seconds at room temperature.

MRID # 497464-03 *Staphylococcus aureus* (ATCC 6538)
MRID # 497464-04 *Escherichia coli* (ATCC # 11229)
MRID # 497464-05 *Shigella boydii* (ATCC 9207)
MRID # 497464-06 *Listeria monocytogenes* (ATCC 19115)

2. The submitted (MRID # 497464-07) efficacy data **support** the use of the product, Backspin No-Rinse FCSS (EPA File Symbol 9480-RG), as a non-contact surface sanitizer against *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538) for a contact time of 15 seconds at room temperature.

VII. LABEL

1. The proposed label claims that the product, Backspin No-Rinse FCSS (EPA File Symbol 9480-RG),, is an food contact sanitizer against the following for a contact time of 1 minute, at room temperature; **are supported** by the applicant's data.

Staphylococcus aureus (ATCC 6538)
Escherichia coli (ATCC # 11229)
Shigella boydii (ATCC 9207)
Listeria monocytogenes (ATCC 19115)

2. The proposed label claims that the product, Backspin No-Rinse FCSS (EPA File Symbol 9480-RG),, is a non-food contact sanitizer against the following for a contact time of 1 minute, at room temperature; **are supported** by the applicant's data.

3. The applicant must make the following changes to the proposed label, as appropriate:

- On page 6 of the proposed label, revise "Helps prevent cross-contamination by killing bacteria on the surface and on the wipe" to read "Helps prevent cross-contamination by killing bacteria on **treated** surface and on the wipe".
- On Page 7 of the proposed label, revise "Simply pull, wipe, and toss to help reduce the risk of cross-contamination" to read "Simply pull, wipe, and toss to help reduce the risk of cross-contamination **between treated surfaces**".
- On page 6 remove "infection prevention" and "foodborne illness protection"
- On page 9 change "...effective against all surface areas to which..." to read "...effective against all hard, non-porous surface areas to which..."